



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/339,818	06/25/1999	MARK E. DAVIS	038134-50010	3090

9629 7590 03/13/2002

MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER

CRANE, LAWRENCE E

ART UNIT	PAPER NUMBER
----------	--------------

1623

DATE MAILED: 03/13/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/339,818	Applicant(s) Davis et al.	
	Examiner L. E. Crane	Group Art Unit 1623	

- THE MAILING DATE of this communication appears on the cover sheet beneath the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE **--3--** MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be filed after six months from the date of this communication.
- If the prior for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 USC §133).

Status

- ☒ Responsive to communication(s) filed on **-02/19/02 (RCE, amdt E & IDS)-**.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

☒ Claims **--1-3, 6-10, 18, 24-27, 30-34, 44 and 46--** are pending in the application. Claims **-48-51 & 56-57-** have been cancelled.

Of the above claim(s) **--□--** is/are withdrawn from consideration.

☐ Claim(s) **--□--** is/are allowed.

☒ Claims **--1-3, 6-10, 18, 24-27, 31-32, 44 and 46--** are rejected.

☒ Claims **--30 and 33-34--** are objected to.

☐ Claim(s) **--□--** are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on **-□-** are ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on **-□-** is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119(a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) **-□-**.
- ☐ received in the national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: **-□-**.

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). **--19--**
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other: **-□-**

U.S. Patent Trademark Office

Office Action Summary

PTO-326 (Rev. 06/19/01)
S. N. 09/339,818

Copy for ☒ FILE ☐ APPLICANT

Part of Paper No. **20**

Art Unit 1623

Claims 4-5, 11-17, 19-23, 28-29, 35-43, 45, 47 and 52-55 were previously cancelled, new claims 56-57 were previously added. Claims 48-51 and 56-57 have been cancelled and claims 1 and 24-25 have been amended as per the preliminary amendment filed February 19, 2002. Amendments to the specification have not been entered for reasons noted below. An Information Disclosure Statement (IDS) filed February 19, 2002 has been received with all cited references and made of record.

Claims 1-3, 6-10, 18, 24-27, 30-34, 44 and 46 remain in the case.

The disclosure is objected to because of the following informalities:

Applicant is respectfully requested to delete the graphs found on pages 53, 57, 58, 59 and 60 from the specification in favor of formal drawings. See 37 C.F.R. §1.58(a).

Applicant's submission of replacement pages for pages 42, 44 and 48 is noted and is incorrect because of the use of the term "Figure" and the insertion of a "Description of Figures" into the specification. Reaction "Schemes" are not graphs and therefore do not need to be separated as "Figures." Applicant is encouraged to amend the disclosure by removal of the instant "Description of Figures" and to amend pages 42, 44 and 48 by replacement of the terms "Figure #" by the terms -- Scheme # -- with appropriate amendments to the disclosure to make references to the Schemes consistent as appropriate.

Appropriate correction is required.

Art Unit 1623

Note to applicant: in order to insure that applicant and examiner are in agreement on the present content of the remaining claims after 5 amendments, examiner respectfully suggests that applicant submit as an appendix to the response to this Office action a clean copy of all claims remaining of record (claims 1-3, 6-10, 18, 24-27, 30-34, 44 and 46).

Claim 25 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10 Claim 25 at line 3 has improper terminal punctuation, and at line 5, lacks proper terminal punctuation.

Applicant's arguments with respect to claims 1-3, 6-10, 18, 24-27, 30-34, 44 and 46 have been considered but are moot in view of the new grounds of rejection.

15 Claims 1-3, 6-10, 18, 24-27, 30-34, 44 and 46 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

20 In claims 1-3, 6-10, 18, 24-27, 30-34, 44 and 46 the generic terminology "co-monomer" and "cyclodextrin copolymer" implies a far wider scope of subject matter than applicant has enabled within the instant specific embodiments. Applicant is therefore respectfully requested to more nearly limit the scope of the instant claims to the
25 scope of the enabled embodiments.

Art Unit 1623

Applicant's arguments filed February 19, 2002 have been fully considered but they are not persuasive.

The instant rejection has been repeated because of the appearance of new art cited in the rejection below. Applicant is encouraged to amend the claims to avoid the prior art because said amendments will probably render this grounds of rejection moot.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Applicant's arguments filed February 19, 2002 have been fully considered but they are not persuasive.

Art Unit 1623

The instant grounds of rejection had been repeated because this case is again under prosecution and therefore possibly not the first application to be sent to issue in the family of applications filed by applicant.

5 Claims 1-3, 6-10, 18 and 44 are rejected under the judicially
created doctrine of obviousness-type double patenting as being
unpatentable over claims 19-23 and 45 of copending Application No.
09/203,556. Although the conflicting claims are not identical, they are
10 not patentably distinct from each other because the subject matter of
the '556 application is so broadly and indefinitely defined that some, if
not all, of the subject matter of the instant application is included within
the vast scope of the '556 claims.

This is a provisional obviousness-type double patenting rejection
because the conflicting claims have not in fact been patented.

15 Applicant's arguments filed February 19, 2002 have been fully
considered but they are not persuasive.

20 The instant grounds of rejection had been repeated because this
case is again under prosecution and therefore possibly not the first
application to be sent to issue in the family of applications filed by
applicant.

25 Claims 1-3, 6-10, 18 and 44 of this application conflict with
claims 19-23 and 45 of Application No. 09/203,556. 37 C.F.R.
§1.78(b) provides that when two or more applications filed by the same
applicant contain conflicting claims, elimination of such claims from all
but one application may be required in the absence of good and
sufficient reason for their retention during pendency in more than one

Art Unit 1623

application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP §822.

5 Applicant's arguments filed February 19, 2002 have been fully considered but they are not persuasive.

The instant grounds of rejection had been repeated because this case is again under prosecution and therefore possibly not the first application to be sent to issue in the family of applications filed by applicant.

10 The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

15 (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

20 (c) the invention was described in a patent granted on an application to another filed in the United States before the invention thereof by applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent."

25 The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject

Art Unit 1623

matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made."

Claims 1-3, 7-10, 18, 24-27, 31-32, 44 and 46 are rejected under 35 U.S.C. §102(e) as being anticipated by, or alternatively under 35 U.S.C. §103(a) as being unpatentable over Kosak '736 (PTO-892 ref. 1449)

BE

The instant claims are directed to copolymers of cyclodextrins and various α,ω -diamino linkers optionally derivatized with biologically active ligands, methods of making, pharmaceutical compositions thereof, and a method of delivering pharmaceuticals therewith.

Kosak '736 at column 15, line 30 through column 16, line 65 and column 20, line 63 through column 26 line 34 discloses copolymers of cyclodextrins and diamines, pharmaceutical compositions thereof, and the delivery of pharmaceuticals therewith which anticipate the instant noted claims because said instant claims do not specify the particular cyclodextrin/diamine co-polymers.

Alternatively, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to read the instant claims to include the cyclodextrin/diamine copolymers of the Kosak '736 reference or to read said reference broadly to include all possible cyclodextrin/diamine co-polymers including those generically disclosed in step "a" of claim 1.

Therefore, the instant claimed cyclodextrin/diamine copolymers, methods of making, pharmaceutical compositions thereof, and methods of pharmaceutical delivery therewith were anticipated by the Kosak '736, or where not anticipated would have been obvious to one of

Art Unit 1623

ordinary skill in the art having the above cited reference before him at the time the invention was made.

Applicant's arguments with respect to claims **1-3, 6-10, 18, 24-27, 30-34, 44 and 46** have been considered but are moot in view of the new grounds of rejection. Additionally, examiner assumes that the parent case of the Kosak '736 reference (noted on PTO-892 in a footnote) has sufficient overlap therewith, and sufficiently predates the instant case's earliest filing date to obviate declarations swearing behind Kosak '736.

Claims **30 and 33-34** are objected to as being dependent on a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and/or amended to overcome rejections under 35 U.S.C. §112.

Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines operated by Group 1600 are **(703) 308-4556** and **703-305-3592**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **703-308-4639**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Geist, can be reached at (703)-308-1701.

Serial No. 09/339,818

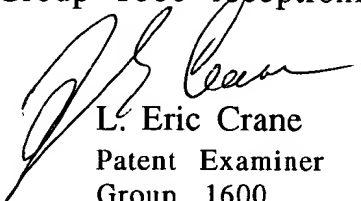
9

Art Unit 1623

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-308-1235.

LECrane:lec

5 03/12/02



L. Eric Crane
Patent Examiner
Group 1600